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| 09/903,831      | 07/11/2001  | Thomas J. Maginot    | 22220-06167         | 1578             |

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EXAMINER

PREBILIC, PAUL B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3738

13

DATE MAILED: 08/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/903,831

Applicant(s)

MAGINOT, THOMAS J.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 47-424 is/are pending in the application.
- 4a) Of the above claim(s) 47-50, 61 and 167-424 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 80-107 and 121-166 is/are allowed.
- 6) ☒ Claim(s) 51-60, 62-69, 72, 73, 108, 111, 112 and 114-116 is/are rejected.
- 7) ☒ Claim(s) 70, 71, 74-79, 109, 110, 113 and 117-120 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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***Election/Restrictions***

Applicant's election with traverse of Group II in Paper No. 12 filed May 28, 2003 is acknowledged. The traversal is on the ground(s) that claims 47-62 are properly classified and examinable with Group II. This is found to be persuasive to some extent and thus, claims 51-60 and 62 have been rejoined. The other claims are withdrawn because they are drawn to a different method, that is, a method of extending an instrument and graft through the femoral artery that is patentably distinct and which would require further consideration and/or search. Since the elected invention is drawn to that of Figure 8, claims 47-50 and 61 have been withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

Claims 47-50, and 61 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

Claims 167-424 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 51-60 and 62-66 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40 of U.S. Patent No. 5,211,683. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim sets are so similar to each other that the present claims can be read on by the patented claims. For this reason, the present claims are considered to be clearly obvious in view of the patented claims.

Claim 51 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5,749,375. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim sets are so similar to each other that the present claims can be read on by the patented claims. For this reason, the present claims are considered to be clearly obvious in view of the patented claims.

Claim 51 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,304,220. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim sets are so similar to each other that the present claims can be read on by the patented claims. For this reason, the present claims are considered to be clearly obvious in view of the patented claims.

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Claims 51-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 5,571,167. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim sets are so similar to each other that the present claims can be read on by the patented claims. For this reason, the present claims are considered to be clearly obvious in view of the patented claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 51-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Kensey (US 4,890,612) where the conduit as claimed is met by the catheter or sheath (26) of Kensey because the catheter or sheath is capable of carrying blood. The instrument that creates the opening at the selected site is the needle within the cannula of Kensey. The anastomosis is formed by sheath (26) of Kensey; see Figure 1 and column 3, line 25 to column 4, line 2.

Claims 67-69, 72, and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Lumley (article entitled "Aorta-bifemoral . . . ") where the orifice as

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claimed is at the top of the single lumen portion of the bifurcation graft and the arms are attached to the femoral and iliac arteries such that at least a portion of the graft tip is within the vessel; see pages 178-180 and pictures 19-30. The blood vessel claimed is the artery of Lumley.

Claims 63 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Montanti (US 3,516,408) where the graft as claimed is the tubing (10) of Montanti, and the apertures as claimed must be inherently formed in Montanti because the tubing is shown both inside and outside the artery (see Figure 4) so it must be that an aperture is present in the artery. The expandable stent as claimed is the cuff (11) of Montanti because the cuff provides support to the vessel and allows blood flow therethrough. The insertion step is inherently made by Montanti (see Figure 4), and the deploying the stent step is done by inflating the cuff. Finally, the second end is attached as claimed when the second cuff is inflated.

Claims 51-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Ablaza (US 4,190,909) where the term "substantially" is considered to be a broad term (see MPEP 2173.05(b)) such that "substantially intact" for the epidermis encompasses epidermal layers that have been incised by a scalpel. The anastomosis is formed at the ends (14) of Ablaza.

Claim 57 is rejected under 35 U.S.C. 102(b) as being anticipated by Sparks (US 3,710,777) where the instrument as claimed is the tunneling tube of Sparks, the conduit as claimed is the fabric tube (27) of Sparks, and the selected location is the artery below the knee; see the figures and columns 3 and 4.

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Claims 108, 111, 112, and 114-116 are rejected under 35 U.S.C. 102(e) as being anticipated by Ehrenfeld (US 5,156,619) where the conduit assembly as claimed is the graft (31) of Ehrenfeld, the resilient member as claimed is the flange portion (33), and the step of placing the resilient portion in the vessel with the rest outside the vessel is inherent to Ehrenfeld because the same elements are shown place that way; see Figures 4 and 5 as well as column 2, lines 33-49 and column 3, line 22 et seq.

With regard to claims 111 and 112, the resilient member is the stitching of the fabric, which has the effect of holding the shape against folding once implanted.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kensey (US 4,890,612) in view a Salky et al (article entitled "Laproscopy For Surgeons"). Kensey has the claim elements as set forth in the rejection of claims 51 and 62 above, but fails to set forth a visualization device as claimed. However, Salky teaches that it was known to use visualization devices in similar surgical methods. Therefore, it is the Examiner's position that it would have been obvious to use a visualization device in the Kensey device in order to better see how the elements are being deployed inside the body. This visualization ability would help the surgeon to see and correct any potential problems during the surgery.

### ***Response to Arguments***

Applicant's arguments filed May, 28, 2003 have been fully considered but they are not persuasive.

In response to the argument that the double patenting rejections are not tenable, the Examiner has modified them. Furthermore, the Examiner asserts that the statements of obviousness made therein are acceptable in that the claim sets are so close that they read on each other. Due to this similarity, no other explanation is needed.

In response to the traversal of Kensey, the Examiner asserts that Kensey reads on the claimed method because it has all the limitations of the claimed method. For this reason, the Applicant's traversal is considered unpersuasive.

### ***Allowable Subject Matter***

Claims 70, 71, 74-79, 109, 110, 113, and 117-120 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 80-107 and 121-166 are allowed over the prior art of record.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The newly cited patents, which were not applied, were the closest found with respect to the foldable or resilient flange as claimed.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure



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outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic  
Primary Examiner  
Art Unit 3738